IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

KATHRYN BENDEL and JONATHAN BENDEL, On Behalf Of Themselves and All Others Similarly Situated	:	
Plaintiffs,	:	**CLASS ACTION COMPLAINT AND JURY DEMAND**
v.	:	
	:	**Case No: 1:10-cv-664**
DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Drive Warsaw, Indiana 46581	:	
Defendant	:	

Plaintiffs Kathryn and Jonathan Bendel, on behalf of themselves and all other United States citizens similarly situated, by and through their attorneys, Burg Simpson Eldredge Hersh & Jardine, P.C., allege as follows:

NATURE OF ACTION

Plaintiff Kathryn Bendel and her spouse Jonathan Bendel bring this Class Action on behalf of themselves and all other similarly situated United States citizens who were recipients, or spouses of recipients, of the DePuy hip replacement devices recently subject to a national recall. The recalled devices, known as the ASR XL Acetabular System, were recalled by Defendant DePuy through an announcement issued on August 24, 2010, which indicated that the device had an unacceptable failure rate resulting in revision surgery in 13% of patients within 5 years.

PARTIES

1. Plaintiffs Karthryn and Jonathan Bendel are residents and citizens of Butler County, Ohio.

2. Defendant DePuy Orthopaedics, Inc. ("DePuy") is an Indiana corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DePuy is a resident and citizen of Indiana.

3. At all times relevant, DePuy was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ASR XL Acetabular System.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between Plaintiffs and Defendant DePuy and the amount in controversy, exclusive of interest and costs, exceeds $75,000.

5. Venue is proper in this district pursuant to 28 U.S.C. § 1961, et. seq., because a substantial part of the events giving rise to this claim occurred in the district.

CLASS ALLEGATIONS

6. Plaintiffs seek to bring this case as a Class Action, under Federal Rule of Civil Procedure 23 (a) & (b)(1),(2) & (3), on behalf of themselves and all others similarly situated as members of the proposed Class, defined as follows: All United States citizens who received an implant of the ASR XL Acetabular System and their spouses.

Rule 23 (a) Requirements

7. The members of the Class are so numerous that joinder of all members is impracticable and are expected be in the thousands.

8. Common questions of law and fact affect the right of each Class Member and a common remedy of medical monitoring is sought for the Class Members.

9. Common questions of law and fact that affect the Class Members include but are not limited to:

a. Whether the ASR XL Acetabular System is defective in design or manufacture;

b. Whether DePuy knew or should have known of the defects in the device prior to its sale and implant in class members;

c. Whether DePuy delayed in recalling the device and failed to provide timely and adequate post-market warning or instruction of the health risk created by this device;

d. Whether medical monitoring must be provided for recipients of the recalled device and what monitoring is necessary;

10. The claims and defenses of the Plaintiffs, as the representative Plaintiffs, are typical of the claims and defenses of the Class.

11. Plaintiffs Kathryn and Jonathan Bendel, as the representative Plaintiffs, will fairly and adequately assert and protect the interests of the Class:

a. Plaintiffs have hired Attorneys who are experienced in prosecuting Class Action claims and will adequately represent the interests of the Class; and

b. Plaintiffs have no conflict of interest that will interfere with the maintenance of this Class Action.

Rule 23 (b) Requirements

12. The prosecution of separate actions by or against individual members of the Class would create risk of inconsistent or varying adjudications with respect to individual members of the Class which would establish incompatible standards of conduct for the party opposing the Class, or adjudications with respect to individual members of the Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests, rendering class certification appropriate under Rule 23(b)(1).

13. Specifically, Plaintiffs seek medical monitoring as a remedy on behalf of persons who have received the recalled DePuy Hip Implant.

14. Defendant DePuy has published a notice of the medical monitoring procedures that all Class Members should be provided by their care givers, which includes radiographic evaluation, blood testing for cobalt and chormium ion levels, and MRI or ultrasounds examinations, to be performed on a recommended schedule.

15. In order to create a medical monitoring program that provides each Class Member with access to care and that enables Defendant to administer a uniform program as a remedy to the Class, certification under Rule 23(b)(1) is necessary. Without such a certification, Class Members who no longer have insurance, or who have inadequate finances to advance the costs, or whose doctors do not agree to

perform the tests, or who have limited access to facilities, would not be assured of obtaining the necessary diagnostic and monitoring procedures.

16. Further, the Defendants have acted or refused to act on grounds generally applicable to the Class as whole by announcing a program that requires Class Members to execute releases to provide their confidential medical records to Defendant DePuy as a prerequisite to Defendant considering whether to reimburse medical costs to the Class Member.

17. Class Members may be deceived into believing that DePuy has actually agreed to advance or reimburse their costs for medical monitoring and revision, when in fact DePuy has only stated that it will use the information obtained through the authorizations to decide whether to pay the "reasonable" medical expenses.

18. In fact, DePuy specifies that before reimbursement of expenses will be provided: "in the event a revision surgery is required, [the records must] confirm that the revision is related to the ASR recall, and not some type of other cause, such as a traumatic fall."

19. Presumably, "some other type of cause" would include not just a "traumatic fall," but also the standard defenses in defective orthopedic device cases, such as allegations of physician error, patient misuse, and alternative causes such as infection or underlying disease. As such, the release provides nothing but a jump start on litigation defenses for DePuy.

20. Further, DePuy intends to use the release to obtain access to the removed devices in order to conduct testing on the devices. But DePuy has made no provision to the Class Members to have their own experts participate in the development of the

testing protocol, to participate in the conduct of the tests, to observe the tests as they are conducted, or to provide the results of the tests to the Class Member.

21. In order to protect Class Members from unfair advantage by Defendant DePuy through the use of medical releases, final injunctive relief or declaratory relief with respect to the Class as a whole is necessary, rendering class certification appropriate pursuant to Rule 23(b)(2).

22. Finally, questions of law or fact common to the members of the Class predominate over questions affecting only individual members, and a Class Action is superior to other available methods for the fair and efficient adjudication of the controversy.

23. Specifically, while each Class Member who received a recalled DePuy Hip Implant will necessarily have some underlying medical condition and will suffer harm due to the implantation of the defective and recalled device, these unique medical issues pertain primarily to damages. The common issues of the defect in the device which each Class Member received, DePuy's knowledge of the defect, DePuy's failure to issue an adequate and timely post-market recall, and DePuy's actions in attempting to obtain medical releases, are the central factual and liability issues that predominate over individual issues of damages.

24. Further, in order to obtain relief in a single forum to all affected claimants, a Class Action is a superior procedural method that will enable the class to obtain comprehensive relief for all Class Members. By individualizing the determination of damages for Class Members, concerns of individuals regarding controlling their litigation will be protected and addressed.

FACTUAL BACKGROUND

DePuy's Recall

25. Defendant's ASR XL Acetabular System is a prosthetic orthopaedic device used in patients in need of a hip replacement.

26. The ASR XL Acetabular system consists of three components: the femoral stem, which is inserted into the femur, the femoral head (or ball), and the metal acetabular cup (or socket), which is what the femoral ball sits inside.

27. On or about March 2010, Defendant DePuy issued a Field Safety Notice regarding its ASR hip replacement system. The Field Safety Notice provided new data which demonstrated that the ASR System had a higher than expected failure rate.

28. On or about August 24, 2010, Defendant DePuy issued a nationwide recall notice for all of its ASR XL Acetabular System. The recall was based on data demonstrating a higher than expected revision surgery rate in 13% of patients within five years.

29. DePuy's recall notice stated that reasons for the higher than expected revisions of the metal-on-metal system included component loosening, component malalignment, infection, fracture of the bone, dislocation, metal sensitivity and pain.

30. In its nationwide recall, Depuy instructed physicians to cease implanting the device. Further, DePuy advised physicians to monitor the medical conditions of patients with the device through specific blood tests, radiographic tests and other diagnostic means. Further, DePuy advised physicians that revision surgery would be necessary in some cases, and that patients must receive revision surgery as soon as problems were detected in order to avoid further complications and injury.

Facts regarding Plaintiff Bendel

31. On or about August 5, 2009, Plaintiff Kathryn Bendel underwent left hip replacement surgery. During the procedure, Plaintiff's physician inserted an ASR XL Acetabular System hip prosthesis manufactured by DePuy.

32. Plaintiff Kathryn Bendel initially did well after the hip replacement surgery, making good strides in her physical therapy and recovery.

33. In approximately March 2010, Plaintiff Kathryn Bendel began having pain and stiffness in her left hip area.

34. Throughout the next several months, Plaintiff's pain and stiffness in her left hip continued to increase. She also began experiencing "popping and grinding" in her left hip.

35. As a result of Plaintiff's continued pain, swelling and stiffness in her left hip, she was unable to continue her physical therapy rehabilitation, she had problems standing for long periods of time, sitting for long periods of time, and walking long distances. Eventually in July 2010, Plaintiff was forced to take a medical leave of absence from her job and she has applied for disability.

36. On or about September 9, 2010, Plaintiff Kathryn Bendel received a notice from her orthopedic surgeon that the hip replacement implant she received in August 2009 had been recalled by DePuy.

37. As a direct and proximate result of Defendant's defective hip replacement implant, Plaintiff Kathryn Bendel will have to undergo radiographic evaluation, blood testing, and an MRI.

38. As a direct and proximate result of Defendant's defective hip replacement implant, Plaintiff Kathryn Bendel will likely have to undergo another surgery to remove and replace the defective DePuy device.

39. As a direct and proximate result of Defendant's defective hip replacement implant, Plaintiff Kathryn Bendel has suffered significant harm, conscious pain and suffering, physical injury, bodily impairment, mental anguish and emotional distress.

40. As a direct and proximate result of Defendant's defective hip replacement implant, Plaintiffs have also incurred medical expenses and other economic harm, including but not limited to lost wages, and will continue to incur such expenses and other economic harm in the future.

41. As a direct and proximate result of Defendant's defective hip replacement implant, Plaintiff Jonathan Bendel has suffered damages and harm, including but not limited to, loss of services, society, companionship and comfort.

Federal Requirements

42. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

43. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

44. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. § 360i.

45. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. 21 U.S.C. § 360j(f).

46. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 *et seq*. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer

must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

47. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

48. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR § 820.3(v).

49. Pursuant to 21 CFR § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

50. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

51. Pursuant to 21 CFR § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

52. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

53. Pursuant to 21 CFR § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

54. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

55. Pursuant to 21 CFR § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

56. Pursuant to 21 CFR § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

57. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

58. Pursuant to 21 CFR § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

59. Pursuant to 21 CFR § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

60. Pursuant to 21 CFR § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

61. Pursuant to 21 CFR § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

62. Pursuant to 21 CFR § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely effect the device's quality.

63. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate compute software for its intended use according to an established protocol.

64. Pursuant to 21 CFR § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

65. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a

high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

66. Pursuant to 21 CFR § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

67. Pursuant to 21 CFR § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

68. Pursuant to 21 CFR § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

f. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;

g. Investigating the cause of nonconformities relating to product, processes, and the quality system;

h. Identifying the action(s) needed to correct and prevent recurrence of noncomforming product and other quality problems;

i. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

j. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

k. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

l. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

Defendant's ASR XL Acetabular System is a 510(k) Approved Medical Device

69. Defendant submitted a § 510(k) premarket notification and obtained marketing approval for its ASR XL Acetabular System from the FDA under Section 510(k) of the Act. See 21 U.S.C. § 360 *et seq*.

70. Under the § 510(k) approval process, the FDA determined that Defendant's ASR XL Acetabular System was "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA).

71. Upon information and belief, Defendant's ASR XL Acetabular System is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

72. Upon information and belief, Defendant's ASR XL Acetabular System is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

73. Upon information and belief, Defendant's ASR XL Acetabular System is adulterated pursuant to 21 U.S.C. § 351 because Defendant failed to establish and maintain CGMP for its ASR XL Acetabular System in accordance with 21 CFR § 820 *et seq*., as set forth above.

74. Upon information and belief, Defendant failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for its ASR XL Acetabular System.

75. As a result of Defendant's failure to establish and maintain CGMP as set forth above, Defendant's ASR XL Acetabular System was defective and failed, resulting in injuries to Plaintiffs, as well as all Class Members.

76. If Defendant had complied with the federal requirements regarding CGMP, Defendant's ASR XL Acetabular System would have been manufactured properly such that it would not have resulted in injuries to Plaintiffs, as well as all Class Members.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY
DEFECTIVE MANUFACTURING

77. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

78. Defendant is the manufacturer, designer, distributor, seller, and/or supplier of orthopedic devices including the DePuy ASR XL Acetabular System.

79. The ASR XL Acetabular System manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendant, was defective in its manufacture and construction when it left the hands of Defendant in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

80. As a direct and proximate result of Plaintiff and Class Members' use of Defendant's ASR XL Acetabular System, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant and/or the failure to comply with federal requirements, Plaintiffs and Class Members suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

81. Defendant's actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY
DESIGN DEFECT

82. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

83. Defendant is the manufacturer, designer, distributor, seller, and/or supplier of orthopedic devices including the DePuy ASR XL Acetabular System.

84. The DePuy ASR XL Acetabular System, manufactured and supplied by Defendant was defective in design or formulation in that, when it left the hands of the Defendant, the foreseeable risks of the product exceeded the benefits associated with

its design or formulation, or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

85. The foreseeable risks associated with the design or formulation of the DePuy ASR XL Acetabular System, include, but are not limited to, the fact that the design or formulation of the ASR XL Acetabular System is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

86. As a direct and proximate result of Plaintiff and Class Members' use of the DePuy ASR XL Acetabular System, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendant and/or its failure to comply with federal requirements, Plaintiffs and Class Members suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

87. Defendant's actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, warranting the imposition of punitive damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY
DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS

88. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

89. Defendant is the manufacturer, designer, distributor, seller, and/or supplier of orthopedic devices including the DePuy ASR XL Acetabular System.

90. The DePuy ASR XL Acetabular System, manufactured and supplied by Defendant was defective in that, when it left the hands of Defendant, it did not conform to representations made by Defendant concerning the product and/or with applicable federal requirements.

91. Plaintiffs and Class Members and/or their physicians justifiably relied upon Defendant's representations regarding the DePuy ASR XL Acetabular System, when they selected these DePuy orthopedic products to be used in surgery.

92. As a direct and proximate result of Plaintiff and Class Members' use of the DePuy ASR XL Acetabular System, and Plaintiffs' and Class Members' reliance on Defendant's representations regarding the character and quality of the ASR XL Acetabular System and/or the failure to comply with federal requirements, Plaintiffs and Class Members suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

93. Defendant's actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, warranting the imposition of punitive damages.

FOURTH CAUSE OF ACTION

NEGLIGENCE

94. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

95. Defendant had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the ASR XL Acetabular System into the stream

of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

96. Defendant failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of the ASR XL Acetabular System into interstate commerce in that Defendant knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

97. Despite the fact that Defendant knew or should have known that the ASR XL Acetabular System posed a serious risk of bodily harm to consumers, Defendant continued to manufacture and market the ASR XL Acetabular System for use by consumers and/or continued to fail to comply with federal requirements.

98. Defendant knew or should have known that consumers such as Plaintiffs and Class Members would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

99. As a direct and proximate result of Defendant's negligence, Plaintiffs and Class Members have suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

100. Defendant's conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and

distribution of the ASR XL Acetabular System when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

101. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

102. Defendant expressly warranted that the ASR XL Acetabular System was a safe and effective orthopedic device for those patients requiring a hip replacement.

103. The ASR XL Acetabular System manufactured and sold by Defendant did not conform to these express representations because it caused serious injury to Plaintiffs and Class Members when used as recommended and directed.

104. As a direct and proximate result of Defendant's breach of warranty, Plaintiffs and Class Members have suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

105. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

106. At the time Defendant designed, manufactured, marketed, sold, and distributed the ASR XL Acetabular System for use by Plaintiff and Class Members,

Defendant knew of the use for which the ASR XL Acetabular System was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

107. Plaintiffs and Class Members and/or their physicians reasonably relied upon the skill and judgment of Defendant as to whether the ASR XL Acetabular System was of merchantable quality and safe for its intended use and upon Defendant's implied warranty as to such matters, including that it was in compliance with all federal requirements.

108. Contrary to such implied warranty, DePuy's ASR XL Acetabular System was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

109. As a direct and proximate result of Defendant's breach of warranty, Plaintiffs and Class Members have suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

110. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

111. In the exercise of reasonable care, Defendant should have known that its ASR XL Acetabular System failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Defendant

negligently misrepresented to Plaintiffs and Class Members and/or their physicians that its device was safe and met all applicable design and manufacturing requirements.

112. Plaintiffs and Class Members and/or their physicians reasonably relied to their detriment upon Defendant's misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products. Plaintiffs and Class Members and/or their physicians reasonably relied upon Defendant's representations that the ASR XL Acetabular System was safe for use.

113. As a direct and proximate result of Defendant's negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its ASR XL Acetabular System Plaintiff and Class Members used Defendant's ASR XL Acetabular System and Plaintiffs and Class Members have suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

114. Defendant's actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

EIGHTH CAUSE OF ACTION

MEDICAL MONITORING CLASS MEMBERS

115. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

116. As a direct result of Defendants' actions and omissions, defective hip replacement prosthesis were implanted in Plaintiffs and Class Members.

117. Plaintiffs seek medical monitoring on behalf of themselves and the Class as a remedy for all persons who have received the recalled DePuy ASR XL Acetabular System.

118. Medical monitoring procedures published by DePuy and sought by Plaintiffs on behalf of themselves and all Class Members include radiographic evaluation, blood testing for cobalt and chromium ion levels, and MRI or ultrasound examinations, to be performed on a recommended schedule.

119. Accordingly, Defendants should be required to establish a medical monitoring problem that includes, *inter alia*:

a. establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of all recipients of DePuy's ASR XL Acetabular System, as frequently as determined to be medically necessary; and

b. notifying Plaintiff Class Members, not just through notices to Doctors, that their ASR XL Acetabular System hip replacement prosthesis requires frequent medical monitoring.

120. Plaintiff and Plaintiff Class Members have no adequate remedy at law in that monetary damages alone cannot compensate them for the risk of future serious and permanent physical injury. Without a Court-approved medical monitoring program as described herein, Plaintiff and the Plaintiff Class Members will continue to face an unreasonable risk of serious and permanent physical injury.

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for judgment as follows:

a. Certifying this action to be a Class Action pursuant to Rule 23(a) & (b) (1), (2), & (3) of the Federal Rules of Civil Procedure, and appointing the named Plaintiffs as proper class representatives of the Class;

b. Awarding Plaintiffs and members of the Class compensatory damages in excess of the minimal jurisdiction amount for this court, as well as punitive damages as a result of the wrongs alleged herein;

c. An injection to prohibit DePuy from communicating with Plaintiffs and Class Members through their physicians.

d. Attorneys' fees and costs;

e. Prejudgment and post-judgment interest; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Respectfully submitted,

/s/ Janet G. Abaray
Janet G. Abaray (0002943)
Melanie S. Bailey (0075821)
BURG SIMPSON
ELDREDGE HERSH & JARDINE, P.C.
312 Walnut Street, Suite 2090
Cincinnati, OH 45202
(513) 852-5600
(513) 852-5611 (fax)
jabaray@burgsimpson.com
mbailey@burgsimpson.com

Of Counsel:
Michael S. Burg
Seth A. Katz
Burg Simpson Eldredge Hersh & Jardine
40 Inverness Drive East
Englewood, CO 80112
(303) 792-5595

JURY TRIAL DEMANDED

Please take notice that the Plaintiffs, on behalf of themselves and all others similarly situated, hereby demand a trial by jury as to all issues in the above matter.

/s/ Janet G. Abaray_____
Janet G. Abaray